

1 Amend 17 Cal. Code of Regs. section 100602 to read:

2 **§ 100602. Invention and Licensing Reporting Requirements.**

3 (a) Prior to an NGA and continuing 12 months after the close of a Grant, a Grantee must
4 have written agreements with Grantee Personnel and Collaborators requiring prompt disclosure
5 to the Grantee of any CIRM-Funded Invention.

6 (b) Within 60 calendar days after a CIRM-Funded Invention has been disclosed to a
7 Grantee, the Grantee must notify CIRM of the CIRM-Funded Invention through the use of the
8 CIRM Invention Disclosure Form, which will be received in confidence by CIRM. The
9 Invention Disclosure Form shall identify the Grant under which the CIRM-Funded Invention was
10 made, the Inventor(s) and the Principle Investigator. The Disclosure shall be sufficiently
11 complete in technical detail to convey a clear understanding, to the extent known at the time of
12 the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical
13 characteristics of the CIRM-Funded Invention. If the CIRM-Funded Invention has been
14 submitted for publication or presentation, then the Disclosure shall identify the publication, the
15 date of the abstract or manuscript or presentation, the submission date and if relevant any
16 publication dates, including publication via the internet.

17 (c) Within 60 calendar days after a Grantee executes an exclusive license agreement,
18 non-exclusive license agreement, material transfer agreement, research collaboration agreement,
19 or any other agreement conveying rights in CIRM-Funded Inventions or CIRM-Funded
20 Technology, a Grantee shall notify CIRM of the execution of such agreement(s) and submit to
21 CIRM a copy of the executed agreement. The notification and agreement(s) shall be marked
22 “Confidential” in accordance with Health and Safety Code section 125290.30, subdivision
23 (e)(2)(B).

(d) A Grantee must submit annually to CIRM during, and for 15 years after, the Project Period of the Grant, an Invention Utilization Report containing the following information:

(1) Grantees must report all patent applications filed which claim, or cite to publications concerning, CIRM-Funded Inventions, including the countries in which application(s) were filed, application serial number(s), status and detailed description(s) of the CIRM-Funded Invention(s); and

(2) Grantees must report the issuance or abandonment of any patent applied for that claims, or cites to publications concerning, CIRM-Funded Invention, including the patent number and date of issuance or abandonment and the countries in which the applications have issued or have been abandoned; and

(3) Grantees must report the total funding from all sources that directly contributed to a CIRM-Funded Invention disclosed or claimed in the patent application, including each co-funder's identity, the dollar amounts each contributed and the dates of contribution. CIRM may audit all such co-funding reports; and

~~(4) A Grantee must report to CIRM the execution of all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and~~

(5) In the event that a CIRM- Funded Invention or CIRM-Funded Technology generates revenue or other consideration (whether from a License Agreement or otherwise), a Grantee must report such revenue or consideration received during the preceding 12 month period or since the last report, whichever is longer.

(6) A Grantee must report the following key progress toward commercialization of a CIRM-Funded Invention or CIRM-Funded Technology including the following:

- 1 (A) Initiation of clinical testing;
2 (B) Initiation of pivotal studies; and
3 (C) Application for marketing approval.

4 (7) Grantee shall have written agreements with its Grantee Personnel, Collaborators,
5 licensees and transferees requiring such third parties to report to the Grantee information
6 described in this subdivision (de).

7 (ed) The Invention Utilization Report shall be marked "Confidential" in accordance with
8 Health and Safety Code section 125290.30, subdivision (e)(2)(B).

9 (fe) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee and
10 Collaborators to ensure compliance with this Chapter. Grantee and Collaborators must maintain
11 and provide such documentation as is necessary to establish compliance. Further, Grantee must
12 ensure that its Collaborators, Grantee Personnel and all Exclusive and Non-Exclusive Licensees
13 maintain such documentation as is necessary to establish compliance.

14 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
15 Safety Code. Reference: Section 125290.30, Health and Safety Code.